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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	13

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/857,333	PHILLIPS ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE f this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,11-14 and 16-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,11-14 and 16-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This Action is in response to the communication filed on 2/3/03, as Paper No. 12. The amendment to the specification has been entered. Claims 1 and 2 have been amended. Claims 1, 2, 11-14 and 16-21 are pending in the application and are examined herein.

2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claim Rejections - 35 USC § 101 & 35 USC § 112

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

5. Claims 2, 12, 14, 17, 19 and 21 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

6. Claims 2, 12, 14, 17, 19 and 21 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

7. The instant claims are drawn to a method/methods for preventing inflammation (i.e. any type of inflammation) in an animal by administering to the animal an effective amount of a

composition comprising a mycobacterial cell wall complex (e.g. see claim 2). However, the specification does not disclose any examples which indicate that the method can be used to prevent inflammation in an animal. The examples only indicate that the composition comprising mycobacterial cell wall complex can be used to induce IL-10 production and thus treat inflammation in animals already having inflammation.

However, the claimed method of preventing inflammation does not constitute a substantial utility because one of skill in the art would not readily recognize that any substance could be used to prevent inflammation, without first completing additional experimentation. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

Additionally, the claimed method of preventing inflammation does not constitute a well-established utility because there is no specific, substantial, or credible utility which is well known, immediately apparent, or implied by the specification's disclosure, alone or taken with the knowledge of one skilled in the art.

The art at the time of filing indicates that inflammation is a complex disease that can be caused by a wide range of different factors. The large number of different causes of inflammation and the wide range of different mechanisms which can cause inflammation make it very difficult to treat. For instance, Heller et al. (Drugs, 1998, Vol. 55, No. 4, pages 487-496) teaches,

> "Many factors contribute to the complex course of inflammatory reactions. Microbiological, immunological and toxic agents can initiate the inflammatory response by activating a variety of humoral and cellular mediators. In the early phase of inflammation, excessive amounts of interleukins and lipid-mediators are released and play a crucial role in the pathogenesis of organ dysfunction. Arachidonic acid (AA), the mother substance of the pro-inflammatory eicosanoids, is released from membrane

> phospholipids in the course of inflammatory activation and is metabolized to prostaglandins and leukotrienes. Various strategies have been evaluated to control the excessive production of lipid mediators on different levels of biochemical pathways, such as inhibition of phospholipase A2, the trigger enzyme for release of AA, blockade of cyclo-oxygenase and lipoxygenase pathways and the development of receptor antagonists against platelet activating factor and leukotrienes. Some of these agents exert protective effects in different inflammatory disorders such as septic organ failure, rheumatoid arthritis or asthma, whereas others fail to do so" (see abstract).

Furthermore, there is no indication in the prior or the post filing art that a "master drug" exists which can be used prevent inflammation. Therefore, one of skill in the art would require additional experimentation in order to accept that the claimed method could prevent inflammation.

Without a clear indication by working example that the claimed method can be used to prevent inflammation in an animal, one of skill in the art would not know how to use the invention to prevent inflammation without performing an undue amount of additional experimentation.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 11, 13, 16, 18 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method for inducing IL-10 production in an animal having inflammation, wherein said method comprises administering to said animal and effective amount of a composition comprising :

(a) a mycobacterial deoxyribonucleotides acid obtained from a disrupted mycobacterium, wherein said mycobacterium deoxyribonucleic acid is preserved and complexed on a mycobacterial cell wall (BCC); and

(b) a pharmaceutically acceptable carrier, wherein the amount is effective to induce the production of IL-10 in said animal.

And also for

A method for inducing IL-10 production in an animal having inflammation, wherein said method comprises administering to said animal an effective amount of a composition comprising Mycobacterium phlei-DNA preserved and complexed and a Mycobacterium phlei cell wall (MCC) and a pharmaceutically acceptable carrier, wherein said amount is effective to induce IL-10 production in said animal.

Does not reasonably provide enablement for the full scope encompassed by the pending claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

The instant claims are drawn to methods of treating inflammation in an animal having inflammation.

The breadth of the claims

The claims are very broad and encompass the treatment of any type of inflammation by administering a mycobacterial cell wall complex to said animal.

The unpredictability of the art and the state of the prior art

As mentioned above, the art recognizes that inflammation encompasses a very broad class of diseases which can be caused by a number of factors. For instance, inflammation can be caused by, among other things, autoimmune dysfunction, infection, as well as toxic agents. These factors can stimulate inflammation through a variety of different inflammatory processes. For instance, humoral or cell mediated responses can stimulate the inflammatory response (see Heller, as indicated above). The humoral and cell mediate response are two distinct inflammatory pathways. There is no indication in the art that any compound can be used to effectively treat any type of inflammation (i.e. inflammation caused by an mechanism).

Working Examples and Guidance in the Specification

The specification discloses that the methods can be effectively used to induce IL-10 production in animals having inflammation, and also indicates the treatment can reduce the amount of inflammation already present in an animal (see example 3). The specification also indicates that the method can reduce the effects of an inflammatory agent (specifically carrageenan) which is administered after the therapeutic composition (see Example 4, p. 8 of the

spec). Although the treatment with the composition prior to the inflammatory agent reduces the inflammatory effect, the treatment does not prevent inflammation.

Quantity of Experimentation

In order to practice the claimed invention to the full scope encompassed by the claims, one of skill in the art would have to perform additional experimentation. The additional experimentation would include experiments to show that administration of the composition could prevent any future occurrence of inflammation in the test subject. This would require years of experimentation to complete, without any guarantee of success.

Level of the skill in the art

The level of the skill in the art is deemed to be high.

Conclusion

Considering the teaching in the art regarding the breadth of the different types and causes of inflammation, the breadth of the claims, the lack of a working example showing prevention of inflammation; and the high degree of skill required, it is concluded that the amount of experimentation required to perform the broadly claimed invention is undue.

Response to Arguments

10. Applicant's arguments, see p. 4-5, filed 2/3/03, with respect to the rejection(s)of claim(s) under double patenting have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 USC 101 (utility) and/or 35 USC 112, first paragraph (enablement) for the reasons set forth above.

11. Applicant's arguments, see p. 5-6, filed 2/3/03, with respect to the rejection(s)of claim(s) under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 USC 101 (utility) and/or 35 USC 112, first paragraph (enablement) for the reasons set forth above.

12. Applicant's arguments, see p. 7-8, filed 2/3/03, with respect to the rejection(s)of claim(s) under 35 USC 112, first paragraph (enablement for different types of mycobacterial cell wall complexes) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of 35 USC 101 (utility) and/or 35 USC 112, first paragraph (enablement) for the reasons set forth above.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DAVE T. NGUYEN
PRIMARY EXAMINER

J. Eric Angell
April 21, 2003